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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,615

01/12/2006

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06-1665

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04/10/2008

EXAMINER

AEDER, SEAN E

ART UNIT

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1642

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,615	<b>Applicant(s)</b> GENKIN ET AL.	
	<b>Examiner</b> SEAN E. AEDER	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

It is noted that the claims of the instant application have been determined to include linking claims. Claim 1 link(s) inventions I-V, as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group I, claim(s) 2-5, 11, 19, and 20, as specifically drawn to methods of oncological and/or infectious and/or somatic diseases by acting on biological targets inside organisms, wherein the biological target is extracellular DNA, wherein extracellular DNA is inactivated by destruction, binding or modification by injecting into a patient a pharmaceutical agent which is capable to destroy, bind, or modify free circulating DNA.

Group II, claim(s) 2, 6, 7, 11, 19, and 20, as specifically drawn to methods of oncological and/or infectious and/or somatic diseases by acting on biological targets inside organisms, wherein the biological target is extracellular DNA, wherein circulating extracellular DNA is inactivated by destruction, binding or modification using extracorporeal blood processing, achieved by immune or affine absorption

Group III, claim(s) 2, 6, 8, 11, 19, and 20, as specifically drawn to methods of oncological and/or infectious and/or somatic diseases by acting on biological targets inside organisms, wherein the biological target is extracellular DNA, wherein circulating extracellular DNA is inactivated by destruction, binding or modification using extracorporeal blood processing, achieved by methods of gravitational blood surgery.

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Group IV, claim(s) 2, 6, 9, 11, 19, and 20, as specifically drawn to methods of oncological and/or infectious and/or somatic diseases by acting on biological targets inside organisms, wherein the biological target is extracellular DNA, wherein circulating extracellular DNA is inactivated by destruction, binding or modification using extracorporeal blood processing, achieved by biological, chemical or photochemical inactivation.

Group V, claim(s) 2, 10, 11, 19, and 20, as specifically drawn to methods of oncological and/or infectious and/or somatic diseases by acting on biological targets inside organisms, wherein the biological target is extracellular DNA, wherein extracellular DNA is inactivated by destruction, binding or modification, wherein the patient is immunized by vaccine containing blood plasma circulating DNA as the antigen.

Group VI, claim(s) 12-18, drawn to a compound possessing desoxyribonuclease activity.

Group VII, claim(s) 21, drawn to methods comprising measurement of patient biochemical factors, differs in that monitoring for control of treatment sizes of molecules, fractions' correlation, binding with proteins, lipids and sugars, nucleotide consequences of free circulating blood plasma DNA are used.

Group VIII, claim(s) 22, drawn to use of blood plasma DNA and extracellular microbial DNA for evaluation of DNA involved in process of diseases' appearance and development, which includes cloning, sequencing, identification of genes, unique and repeated sequences with their future studying.

The inventions listed as groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VIII appears to be that they all relate to the special technical feature of a treatment method by acting on extracellular DNA inside organisms.

However, Gocke et al (US 6,521,409; 2/18/03) teaches a treatment method by acting on extracellular DNA inside organisms in order to clarify when to initiate various therapies (see paragraph spanning columns 8 and 9, in particular).

Therefore, the technical feature linking the inventions of groups I-VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

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Accordingly, groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sean E Aeder/  
Examiner, Art Unit 1642